

REMARKS

Status of the claims

Claims 1 and 5-11 are pending in the application. Claims 7-8 are withdrawn. Claims 1, 5 and 9-11 are rejected. Claim 1 is amended.

Claim Amendments

Claim 1 has been amended to include a step of transducing energy added to the reaction vessel into thermal energy. Also, claim 1 is amended to clarify that the transduced "thermal" energy is applied to the reactants and/or the medium in the reaction vessel. Claim 5 is amended to clarify that the energy is the added energy of the included method step. These amendments overcome the 35 U.S.C. §102(b) rejection. No new matter was added in this amendment.

Obviousness-type double patenting

Claims 1 stands provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claim 45 of copending application USSN 10/774,320. Enclosed is a terminal disclaimer in compliance with 37 CFR 1.321(c). Accordingly, Applicants respectfully request that the rejection of claims 1 under the nonstatutory obviousness-type double patenting be withdrawn.

Claim Rejections under 35 U.S.C. §102(b)

Claims 1, 5, 6 and 9-11 are rejected under 35 U.S.C. §102(b) as being anticipated by **Bystryak et al.** (US 5,776,703) in view of **Morton** (1934, abstract only). Applicants respectfully traverse this rejection.

The Examiner states that **Bystryak et al** discloses a method to photochemically amplify the horseradish peroxidase-mediated immunosorbent assay (ELISA). The method comprises a dark reaction wherein a first antibody (A1) having an affinity for an analyte, such as antigen (An) is bound to a solid

support; the bound first antibody is contacted with material suspected of having antigen to form a complex first antibody-antigen. The complex is then reacted to with an enzyme-tagged antibody (EA2), wherein the second antibody also has affinity for antigen, to form a second complex: EA2-A1-An. Further, the Examiner states, the enzyme can be horseradish peroxidase. The second complex is reacted with o-pheylenediamine (o-PD) and hydrogen peroxide so that o-pheylenediamine is converted to 2,3-diamino-phenazine (DAP). The amount of DAP generated is proportional to the EA2-A1-antigen complex formed, and thereby measures the analyte in the sample.

Hence, the Examiner states this disclosure meets the limitations of claim 1 wherein the reactants and the means are combined in a reaction vessel. The sensitivity of the dark reaction is increased by placing the dark reaction in a vessel having an irradiation means and then irradiated from about 400nm-500nm, thereby initiating the production of DAP and enhancing the optical density signal measured by the spectrophotometer. The disclosure of radiation of wavelength 400-500nm meets the limitations of instant claims 5 and 6. Further, the Examiner states this disclosure meets the limitations of instant claim 1 wherein the energy is applied to one or more of the reactants which results in an increase in the amount of DAP. Although **Bystryak** is silent regarding the alteration of the molecular state of the reactants upon irradiation, **Morton** discloses benzene and its derivatives, including o-PD, absorb energy in the range of 260-405 nm, which results in a change in vibrational sub-levels. The Examiner states that the methods of **Bystryak** practices the same physical steps as claimed: reactants and a medium for ELISA placed in a reaction vessel having an irradiation means. The reactants are irradiated, they absorb energy and achieve an increased energy state thereby increasing the rate of formation of the product of the ELISA reaction. The irradiation of the substrate o-PD may result in the alteration of its vibrational state, as in the instant claims 9-10. Hence, the Examiner concludes that the transition state of the reactant is altered as in instant claim 11.

The Applicants submit that **Bystryak et al** teach an assay for

increasing sensitivity for the detection of haptens based on the formation of a complex of the entity to be measured with another entity, tagging the thus formed conjugate with an oxidizing entity, reacting the resultant entity with a redox substrate to form a product which is photosensitive, and irradiating the same, thus enhancing the sensitivity of the assay. **Bystryak et al** refers to a non-thermal photochemical reaction used in an immunoassay. The reaction, as taught by **Bystryak et al**, requires photons with an energy equal to or greater than the bandgap of the transition induced in the molecule (DAP). Hence, **Bystryak et al** teach applying radiant energy that has a wavelength in the range of the optical absorption bands of DAP. The result of this reaction is to increase the DAP on the antigen/antibody complex thus providing greater optical density per complex thereby increasing the sensitivity of the measurements. Hence, **Bystryak et al** teach a method of detecting an antibody/antigen complex.

Amended claim 1 of the instant invention teaches that the instant invention provides methods of enhancing/accelerating reaction catalysis by adding thermal energy. **Bystryak et al**, as mentioned *supra*, teach non-thermal photochemical reactions. The instant invention teaches transducing energy, e.g., electromagnetic or mechanical energy, added to the reaction vessel into thermal energy to increase the yield of the product by altering the molecular state of the reactants via the thermal energy and without adding any more reactants, contrary to the teachings of **Bystryak et al**. Further, unlike **Bystryak et al**, the instant invention does not require for the added energy to be directly absorbed by the reactants. The instant invention teaches increasing the sensitivity of an ELISA by placing the reaction mixture in a microwave (Example 4). The microwave energy is absorbed by the solvent (water) in the reaction mixture and not by the reactants. In the instant invention, a thermal mechanism induced with energy less than the absorption bandgap of the reactants accounts for this phenomenon. Further, Examples 7 and 8 of the instant invention teach mechanisms where reaction rates were increased but not via absorption of energy by the reactants. Pressure waves employed as energy, in these examples of the instant invention,

are insufficient to induce a change in the quantum state of the molecule as described by **Bystryak et al.** Further, in Example 5, the instant invention teaches adding a dye for the absorption of electromagnetic energy thus heating up the reaction mixture and hence increasing the rate of the reaction. The dye, as taught by the instant invention, does not complex with the reactants. Thus, in the instant invention the catalyst is present in or is attached to the reaction vessel in such a way that reactants are in contact with the catalyst. **Bystryak et al** teach complexing the catalyst to the reactants and not to the vessel. **Bystryak et al** teach increasing sensitivity of a reaction based on the formation of a complex of the entity to be measured with another entity. The instant invention teaches increasing an energy state of reactants by adding energy.

Hence, **Bystryak et al.** do not anticipate the instant invention and a combination of **Bystryak et al** with **Morton**, clearly would not remedy the deficiency. Therefore **Bystryak et al.** in combination with **Morton** is not a proper reference under 35 U.S.C. §102(b). Original claims 5-6 and 9-11 depend directly or indirectly from amended independent claim 1. These dependent claims further limit the applied energy (claims 5-6) and the molecular state (claims 9-11).


Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 1, 6 and 9-11 under 35 U.S.C. §102(b) be withdrawn.

This is intended to be a complete response to the Office Action mailed February 07, 2007. Applicants submit that claims 1, 5-6 and 9-11 are in condition for allowance and respectfully request that claims 1, 5-6 and 9-11 be passed to issuance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Applicants enclose herewith a Terminal Disclaimer and a Petition for One Month Extension of Time. Please charge the \$65 fee to submit a Terminal Disclaimer under 37 C.F.R. §1.20(d) and the \$60 extension fee under 37 C.F.R. §1.17(a) to the credit card identified on the enclosed Form PTO-2038.

Only in the absence of this Form, please debit any applicable fees from Deposit Account No. 07-1185 upon which the undersigned attorney is allowed to draw.

Respectfully submitted,

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